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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,203

10/20/2003

Kenneth E. Kadziauskas

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33357 7590 06/22/2009
ABBOTT MEDICAL OPTICS, INC.
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EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/690,203	Applicant(s) KADZIAUSKAS ET AL.	
	Examiner Manuel A. Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27, and 32-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

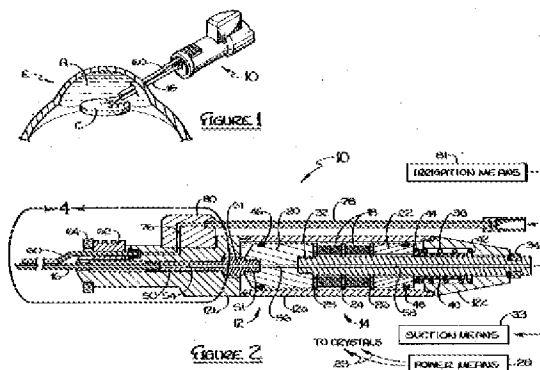
DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-27 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Parisi** (US 4,861,332) in view of **Scheller** et al. (US 4,933,843; hereafter Scheller), **Tu** (US 5,968,005), and in further view of **Broadwin** et al. (US 4827911; hereafter Broadwin).



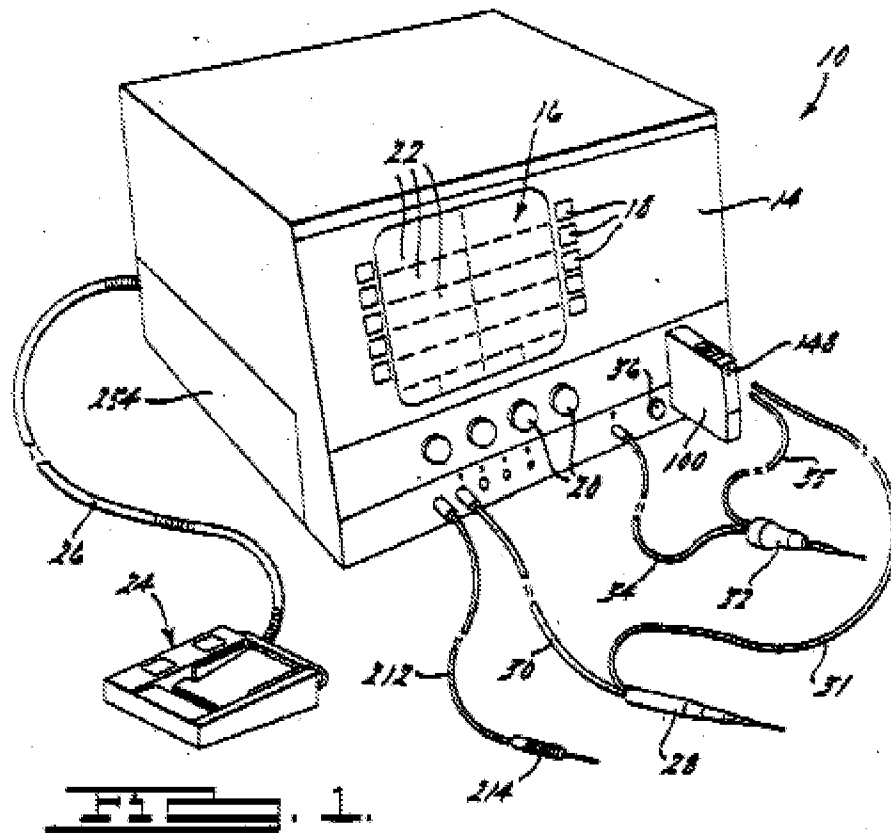
In figures 1 and 2 above, the Parisi patent shows a phacoemulsification system having a handpiece and having the capability of providing power to the handpiece, and additionally, providing irrigation fluid and an aspiration source. Furthermore, the specification of Parisi states in column 6, line 61:

"[i]n summary, the ultrasonic probe 10 of the present invention, having uniform and constant pre stress compression loading of the piezoelectric transducer 18 and having parallel irrigation with the substantially straight-through aspiration through the operative

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tip 16, provides significant advantages over the prior art ultrasonic probes. The resilient compression coil spring 64 provides uniform compression loading which avoids breakage of the transducers during mounting, due to localized stresses, during mounting or operation of the transducers. Enhanced electromechanical coupling is also provided for improved operating efficiency at lower temperatures".

Accordingly, the teachings of Parisi emphasize the importance of temperature control, and moreover, the use of an irrigation system to control temperature at the distal tip of the handpiece to prevent damage to tissue. Parisi does not disclose a control console or an algorithm to control temperature in the area of application within the body. However, the use of a control console to control a phacoemulsification system would have been considered conventional in the art based on the teachings of Scheller.



In figure 1 above, Scheller shows a control console for a phacoemulsification system. The control system is programmable by the user by inserting a preprogrammed key into the system console. Moreover, the specification in column 1, lines 28-37, states that:

“[t]he conventional console also has push button switches and adjustable knobs for setting the desired operation characteristics of the system. The conventional control system usually serves several different functions. For example, the typical ophthalmic microsurgical system has both anterior and posterior segment capabilities and may include a variety of functions, such as irrigation/aspiration”.

Based on the above teachings, it would not be unreasonable to conclude that control consoles can be used to program an irrigation and aspiration system in accordance with the particular requirements of the medical procedure. Scheller does not expressly disclose an algorithm to control the temperature at the distal tip of the handpiece using the irrigation and aspiration. However, such particular algorithm would have been considered conventional in the art as evidenced by the teachings of Tu and Broadwin

The Tu patent discloses a temperature control algorithm. In column 4, lines 37-53, the specification of this patent states "[a] temperature sensing means 12 is disposed close to the electrode means 5. An insulated temperature sensor wire means 13 passes from the temperature sensing means at the distal end, to an external temperature control mechanism through the outlet connector 6. The RF energy delivery is controlled by the measured temperature and by a close-loop temperature control mechanism and/or algorithm".

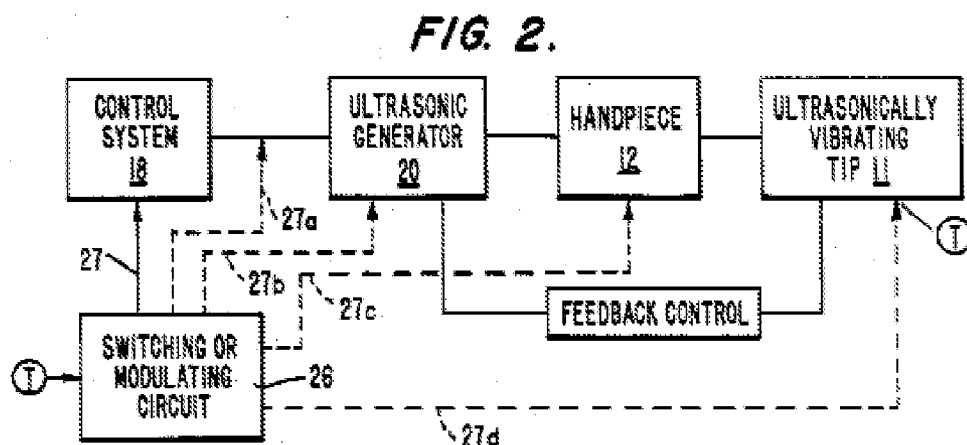
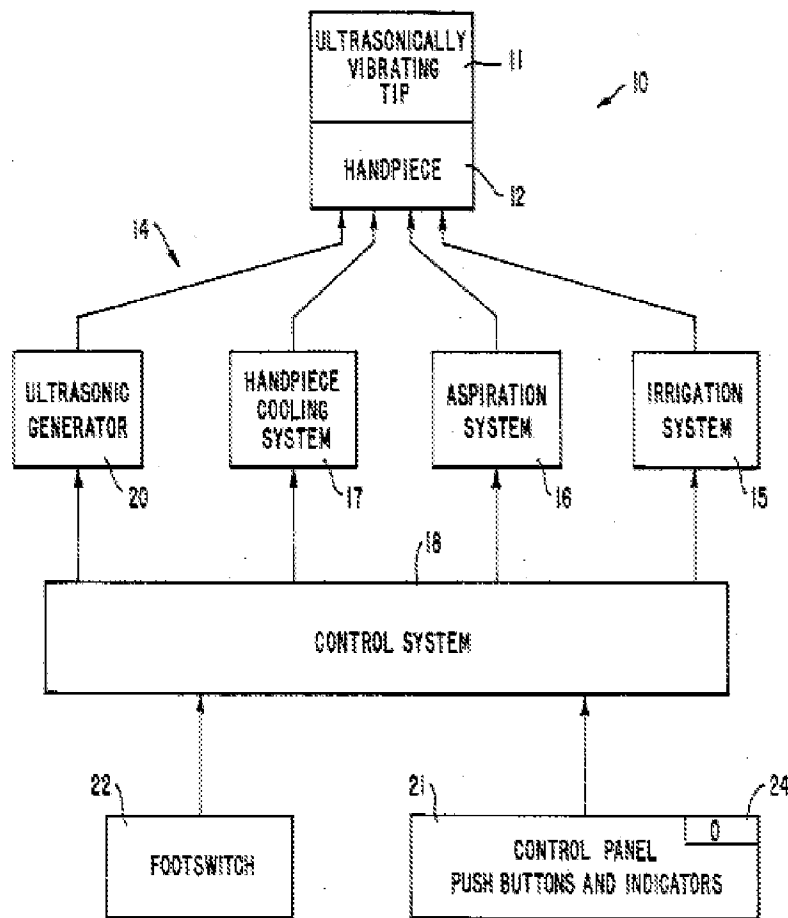


FIG. 1.
(PRIOR ART)



In figures 1 and 2, the Broadwin patent shows an ultrasonic system for regulating fluid flow and energy into body tissue comprising of handpiece, a control console, and most importantly, an algorithm to maintain tissue temperature within a predetermined range. The specification states:

Thus, it is another overall objective to provide a method and ~~apparatus~~ apparatus for accurately controlling energy as it is transmitted to ~~target~~ so as to enhance its cutting action in

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both hard [a]nd soft [tissue] while maintaining the [temperature] in the surrounding [tissue] below a preset level. In this context it is desirable to utilize a higher stroke level than can otherwise be surgically tolerated without exceeding the allowable average energy, i.e., to simulate the effect of a high stroke level with a lower stroke level. It is also an objective to improve the visibility and [control] of the cutting action when fragmenting soft [tissue] and to utilize higher stroke levels for improved but safe fragmentation without damage to surrounding [tissue] areas as is characteristic of prior art devices.

Additionally, the specification also states:

Such a method and apparatus according to the invention [control] the fragmentation rate of the [ultrasonic] surgical system 10 wherein a surgeon may select the duty cycle or, the duty cycle may be set electronically or even automatically in response to a derived [control] signal to vary the duty cycle. Moreover, the use of a variable duty cycle by varying the relative amplitudes and periods of the application of the high and low strokes of the vibrating tips 11 acts to [control the temperature] of the tissues surrounding the operating areas. Such [control] of the duty cycle will thus permit hard [tissue] to be fragmented by increasing the stroke to a high amplitude for some limited period within the period of the modulating wave while permitting the heat transferred to the [tissue] to be controlled. It is known that when [tissue] is being fragmented, [ultrasonic] energy is transferred from the tip of the [handpiece to the tissue]. Some portion of the energy transferred is used to fragment the [tissue], while a subportion is absorbed by the [tissue] and results in heating it. In an extreme case, [tissue] may be burned or vaporized creating an undesirable effect. Thus, a [control] of the type utilized in this invention prevents overheating of healthy tissues to the point of destruction.

Based on the above evidence and the above observations, for a person of ordinary skill in the art, modifying the apparatus disclosed by Parisi with a control console, as taught by Scheller, and furthermore, programming said control console to control the temperature at the distal tip of the handpiece, as taught by Tu and/or Broadwin, would have been considered obvious in view of the proven conventionality

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of these particular enhancements, and moreover, because such algorithm would have enhanced the accuracy of the overall system by preventing the destruction of good tissue by controlling the temperature in the area of application in the body.

Response to Arguments

Applicant's arguments filed on 11/10/2008 have been fully considered but they are not persuasive. The examiner notes for the record, that the term "phacoemulsification" does not provide any structural limitations to distinguish the invention from the prior art used in the pending rejections. Additionally, the use of an ultrasonic system in the eye is considered by the examiner as an intended use, and therefore, does not provide patentable weight to the pending claims. Finally, since the examiner of record included the Broadwin patent in the above rejection, this office action is not a final office action. The examiner respectfully invites applicant to provide comments pertaining to the merits of the newly presented evidence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763